REMARKS

Applicants respectfully request reconsideration of the present application.

I. DISPOSITION OF THE CLAIMS

Claims 1, 3, and 8 are being amended. Claims 4 and 12 are being canceled. New claim 13 has been added to limit claim 9 to "Ginkgo biloba". No new matter is added.

Upon entry of this amendment, claims 1-3, 5-11, and 13 will be pending and under examination. No claims are withdrawn

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate status identifier.

II. STATEMENT OF SUBSTANCE OF INTERVIEW UNDER 37 C.F.R. § 1.133(B)

Applicants' Representative thank Examiner Sean M. Basquill and Primary Examiner Brandon J. Fetterolf for the helpful and courteous interview of November 25, 2008. During the interview, the cited references US 6,056,949 ("Menzi"), US 4,960,596 ("DeBregeas I"), and US 6,228,395 ("DeBregeas II") were discussed. Applicants' Representative proposed amending the claim 1 to introduce the limitations "pharmaceutically acceptable excipient," "dry plant extract", and "powder coating". The substance of the interview is set forth in more detail below.

III. INDEFINITENESS

Applicants have obviated by amendment the rejections of claims 3-4 and 12 for indefiniteness under 35 U.S.C. § 112, second paragraph.

The Office rejected claim 3 for the limitation "which is coated with 80% by weight of starch", rejected claim 4 for lacking antecedent basis in claim 1, and rejected claim 12 for its limitations regarding layers. Office Action, page 3, paragraphs 1-3.

Claim 3 has been amended to delete "which is coated with 80% by weight of starch".

Claims 4 and 12 have been canceled.

IV. OBVIOUSNESS

The claims stand rejected as obvious over US 6,056,949 ("Menzi"), Nissenson et al., West. J. Med. 1979, 131:227-284 ("Nissenson"), US 4,960,596 ("DeBregeas I"), US 6,030,621 ("De Long"), and US 6,228,395 ("DeBregeas II").

The amendments herein clearly overcome this ground of rejection for the following reasons.

Claim 1 as amended includes the following new limitations further distinguishing Menzi, DeBregeas I, and DeBregeas II:

- "wherein said plant substance is a dry plant extract"
- "wherein said layer is applied to said neutral core by powder-coating"

Menzi does not disclose powder-coating a dry plant extract. Instead, Menzi states that the invention involves "spraying a flavorant or odorant emulsion" (emphasis added; column 1, lines 60-61). Spraying an emulsion is a completely different process from powder-coating.

Menzi emphasizes that the disclosed granulated material is "practically dust-free" (Abstract, lines 2-3, and column 1, lines 6-7) or "substantially dust-free" (column 3, line 9). This would discourage a person of ordinary skill in the art from modifying Menzi by applying a layer of powder via "powder-coating" as claimed.

Menzi indicates a preference for liquid flavorants over a "dry plant extract" as claimed. Menzi's Examples 1-5 disclose liquid flavorants where the physical form is specified. For example, Menzi refers to lemon oil, lime oil, and lemongrass oil + pepper oleoresin (column 3, lines 26-27, 48, and 64).

For DeBregeas I and II relating to Diltiazem, powder-coating would be an unlikely choice given the associated technical difficulties.

The powder-coating process is very difficult to be carried out in comparison to the liquid spray process of DeBregeas I and II with Diltiazem, as the dry extract is very hygroscopic and

sticky and thus its handling is difficult. A person of ordinary skill in the art would thus certainly have been motivated to use an alcohol solution of the extract, which is more easily handled.

Finally, Applicants note that the aim of the present invention is to provide a formulation of plant extracts which has reproducible proportion and uniform and reproducible release profile (see page 3, paragraph [0008], and page 4, paragraph [0011]). In particular, the present specification discloses that the claimed invention "allows better reproducibility of the proportion" (page 8, paragraph [0032]).

However, none of the cited references refers to such a problem to be solved.

Indeed, the aim of Menzi is to provide a flavorant and odorant granulates which are mechanically stable, free-flowing, and practically dust-free. Moreover, the aim of DeBregeas I and I1 is to provide a Diltiazem formulation with a slow or sustained release in order to reduce the number of times the medicine needs to be taken per day (see abstract). Finally, the aim of De Long is to provide an extract of Ginkgo Biloba with a higher content in active compounds.

Thus, the skilled person would <u>not</u> be motivated to use the knowledge of the four cited references (Menzi, DeBregeas I and II, De Long) to prepare the formulations of the invention, because none of these references refers to the same problem to be solved.

Moreover, it is important to note that a granule as described in Menzi comprises several cores coated with a flavorant or odorant emulsion forming thus a sort of matrix around the cores. According to Menzi's Figure 1, the size and the form of the cores are variable which implies that the content of the flavorant or odorant substance will be different from a granule to another:

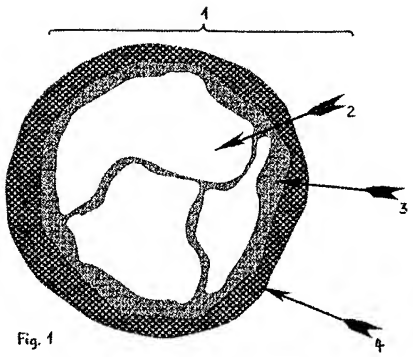
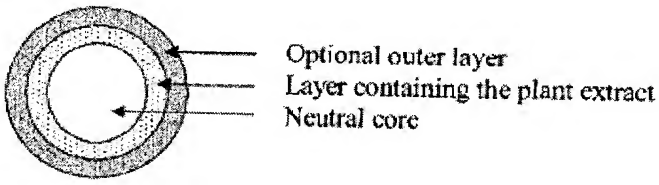


Fig. 1

Menzi's Granules

Consequently, the granules described in Menzi do not allow for obtaining granules with reproducible proportion of the active substance, which is the aim of the present invention (specification, page 2, paragraph [0032]).

In the present invention, the neutral cores are almost spherical and the granules have the following structure, which allows the reproducible content of the plant extract:



Claimed Granules

Regarding the preamble phrase "pharmaceutical formulation", this now clearly limits claim 1, because claim 1 as amended recites in its body "pharmaceutically acceptable excipient". See M.P.E.P. § 2111.02, citing *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333 (Fed. Cir. 2003) (in a claim directed to a method of treating or preventing pernicious anemia in humans by administering a certain vitamin preparation to "a human in need thereof," . . . the claims' recitation of a patient or a human "in need" gives life and meaning to the preamble's statement of purpose).

Consequently, the previously presented arguments based on the claimed invention being a "pharmaceutical formulation" now clearly apply. Specifically, the granules of Menzi are not intended for a pharmaceutical use. Menzi relates to aromatic granules. The applications taught by Menzi are: tea bags, instant drink powder, chewing gum, hard and chewable sweets, or ice cream with chocolate coatings (see example 6). The aromatic granules of Menzi are used as a flavorant vector incorporated into products to give a flavor to said product. Menzi does not teach nor suggest that the granules may be used per se as a formulation having a pharmaceutical activity. In other words, Menzi fails to teach or suggest the pharmaceutical formulation in the form of granules as recited in claim 1.

For all the reasons given above, Applicants submit that the obviousness rejection has been obviated by the present amendment.

CONCLUSION

Applicants respectfully request entry of this Amendment and allowance of the application.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 23-DEC-2008

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